her rejection pursuant to either 35 USC §102 or 35 USC §103. Applicants thank the Examiner for her reconsideration and withdrawal of the rejection.

Applicants also note that the Examiner has characterized the currently pending claims as constituting both method and composition claims. In fact, the pending claims are solely drawn to methods using an RAR antagonist having specific RAR modulating activity. There are no composition claims currently pending.

Rejections Pursuant to 35 USC §112(1)

The Examiner has rejected claims 13-28, alleging that the pending method claims are not enabled by the specification to that a person of ordinary skill in the art could make or use them.

In support of her position, the Examiner has cited factors set forth in *Ex parte Forman*, 230 USPQ546 (Bd. Pat. App. & Int. 1986) and later cited in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) in an attempt to establish that compounds that are RAR specific and have RARβ antagonist activity (i.e., those used in the claimed methods) can only be found through undue experimentation.

Interestingly, the Examiner concedes that the RAR antagonists disclosed in the patents incorporated by reference within this application are enabled. October 31, 2002 Office Action at page 2. Such compounds constitute many thousands of structurally diverse compounds, including: aryl-and heteroarylcyclohexenyl substituted alkenes, benzo 1,2-chrom-3-ene and benzo1,2-thiochrom-3-ene compounds, N-aryl substituted tetrahydroquinolines, and aryl-substituted and aryl and (3-oxo-1-propenyl)-substituted benzopyran, benzothiopyran, 1,2-dihydroquinoline, and 5,6-dihydronaphthalene derivatives. Additionally, and as pointed out in past replies to Office Actions, screening methods for finding those antagonists that inhibit RARβ, such as the transactivation assay described on page 13, lines 9 et seq., are also described in detail in the patents incorporated by reference (see, for example, US Patent 5,877,207, column 107, lines 12-59). Those of ordinary skill in the art clearly know that it is merely a matter of routine to test panels of compounds in assays such as the transactivation assay, which are amenable to high throughput computerized use. Such does the present patent application disclose in light of the state of the art known to the ordinary skilled artisan.

Applicants again note that a new use is statutory subject matter, whether the materials used in it are old or not.

The Federal Circuit case law used by the Examiner in an attempt to show "undue experimentation", (e.g., *In re Wands*) actually supports Applicants' point of view. In *Wands*, the Court of Appeals for the Federal Circuit reversed the Board of Appeals and Patent Interferences' rejection of claims drawn to an immunoassay method using anti-hepatitis surface antigen (HSA) antibodies. The only issue was whether, in light of only a single deposit of a hybridoma cell line, and in the lack of a single example showing the structure of a high affinity anti-HAS antibody, to obtain such antibodies would require undue experimentation thus rendering the claims non-enabled. In reversing the Board on this point the *Wands* court held that since the antibodies could be made using publicly available starting materials and well know methods through "only routine screening". The *Wands* court stated "a considerable amount of experimentation is permissible if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Wands*, 8 USPQ2d at 1404. Applicants again submit that the thousands of RAR antagonists enabled by the present specification and the clear description of a simple method for screening such compounds for RAR beta selective activity makes the present claims more clearly enabled than those of Wands.

More recent case law continues to support the *Wands* doctrine. In *Johns Hopkins University v Cellpro, Inc.*, 47 U.S.P.Q.2d 1705 (Fed. Cir. 1998), the Federal Circuit again upheld the patentability of claims in the chemical and biological arts challenged for lack of enablement. These claims were drawn to the broad genus of antibodies binding to a given ligand. The specification cited methods of making such antibodies, and gave a single example of such an antibody. The *Johns Hopkins* court quoted and cited with approval its earlier case law illustrating that a considerable amount of experimentation is permissible to comply with the enablement requirement, if it is merely routine. *Id.* at 1719 (citing *PPG Industries, Inc. v Guardian Industries, Corp.*, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996); *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). The *Johns Hopkins* court thus found that the claims were enabled.

Thus, the present claims meet the statutory requirements for enablement. The specification,

in light of the prior art, would permit the person of skill in the art to carry out the claimed method. For this reason, the Applicants respectfully request the Examiner to reconsider and withdraw this final ground for rejection, and permit the claims to proceed to issue.

CONCLUSION

For these reasons, Applicants respectfully submit that the claims are in condition for allowance, and respectfully request that the Examiner issue a Notice to that effect. Should any fees be due in with this Reply, please use our Deposit Account No. 01-0885.

Respectfully submitted,

Dated: 1/31/03

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MARKED UP VERSION OF THE CLAIMS

13. (Amended) A method for the treatment or prevention of alveolar destruction in a mammal comprising the step of administering a therapeutically effective amount of an RAR antagonist having specific RAR modulating activity to said mammal.